REMARKS

The Office Action of April 1, 2008, has been received and carefully reviewed.

Claims 11-21 are currently pending in the application. Claims 11, 19 and 20 have been amended. No new matter has been added by these claim amendments.

The Examiner objected to claim 19 due to a redundancy in the preamble of the claim. Claim 19 has been amended and the objection has been rendered moot.

Rejection under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 11-17, and 21, under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner objected to the phrase "and the balance of a vehicle" as unclear. Applicants have amended this claim with "the balance of said solution is comprised of a vehicle" in both claims 11 and 20, to further clarify that which Applicants consider to be the invention. Support for this amendment can be found at page 12, line 4, and claim 2 of the specification. Applicants respectfully request the Examiner to withdraw the rejection as moot.

The Examiner also objected to claim 20 as reciting a use without inclusion of any steps to set forth the actual use of the solution. Applicants have amended claim 20 to positively recite steps of the method of use, and respectfully request the Examiner to withdraw the rejection as moot.

Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 11-21 under 35 U.S.C. §103(a), as unpatentable over USPA 2002/0037943 to Madsen, in view of USPA 2004/0043052 to Hunter et al. According to the Examiner, Madsen discloses in Examples 2 and 3, a cross-linked hydrophilic polymer coated catheter, and a method of coating said catheter by applying a polymer solution to the catheter, followed by subsequent evaporation of the solvents, and then curing. The coated catheter of Madsen is further sterilized, while the coating is wetted with a wetting liquid (a PVP solution). The Examiner admits that Madsen teaches the use of a plasticizer, but fails to teach a plasticizing solution having the parameters claimed by Applicants. The Examiner offers Hunter et al. for teaching the use of a specific plasticizer allegedly having the same parameters as claimed by Applicants. The Examiner concludes that it would have been obvious, for one of ordinary skill in the art, at the time the invention was made, to modify the type of plasticizer used in Madsen, with the plasticizer of Hunter et al., in order to attain the claimed coating with the desired parameters. Applicants respectfully traverse this rejection.

In Examples 1 through 3 of Madsen, a process for coating a catheter with a two-layer crosslinked, hydrophilic polymer coating is taught. The catheter is dipped in a solvent mixture of PVP, or a mixture of hydrophilic polymers and additives, and then exposed to UV light so as to crosslink the polymers on the surface. The coatings are later dried. The catheters are then further processed by being placed in a second wetting solution containing PVP, and sterilized while in this solution for storage. It is

important to note that the catheter is stored in the sterile wetting solution, in a sealed package for use (paragraphs [0093] - [0107]).

In view of the above, Applicants' claimed method is first distinguished from Madsen, because Madsen teaches that plasticizers may be part of the wetting liquid (see sections [0067]-[0071]), and not as a part of the polymer solution used for coating the catheter with the hydrophilic polymer, as in Applicants' invention.

Further, Madsen teaches that the wetting solution may contain plasticizers such as diethlyene glycol, glycerol, phthalates, sorbitol or the like (paragraph [0070]). However, Applicants surprisingly found that plasticizers such as those taught in Madsen, do not result in coatings having sufficient integrity or bonding strength for Applicants' intended purpose (page 3, lines 29-34). Applicants found that when used for plasticizing the coating in the polymer coating solution, the plasticizers taught in Madsen reduced coherence and abrasion strength of the resulting coating (page 8, lines 3-5).

Applicants surprisingly found that the choice of plasticizer was critical in plasticizing the coating formed from the polymer solution (page 7, lines 21-23). Applicants teach that the claimed plasticizers of Applicants' invention do not retard water uptake in the coating, and can be characterized by their high boiling points, large water solubility, and a Hansen parameter of less than 20 (page 8, lines 6-16). Thus a further distinction between the teaching of Madsen and Applicants' claimed invention is that the group of plasticizers taught in Madsen are not suitable for Applicants' claimed invention.

Turning to Hunter et al., Applicants note that Hunter et al. is not specifically directed to hydrophilic coatings of medical devices, but rather coatings which contain chemotherapeutic agents that can inhibit, reduce or prevent the growth of bacteria, fungi, or viruses, on the surface of the coated devices (paragraphs [0010] - [0011]). The portion of Hunter et al. cited by the Examiner is directed generally to medical devices [0095], and to polymer coatings having plasticizers such as "glycerol or triethyl citrate" [0109]. Applicants respectfully point out, however, that glycerol, as stated above with regard to Madsen, is not an acceptable plasticizer for Applicants' claimed invention. Hence, the description of coated medical devices using glycerol and triethyl citrate as plasticizing agents in Hunter et al., can be understood as merely a general recitation of known prior art polymers and plasticizers, and actually teaches away from Applicants' claimed method.

Furthermore, careful reading of the preceding paragraph [0108] of Hunter et al., teaches that the polymer coating being discussed in [0109] is not intended as a low-friction, lubricious hydrophilic polymer coating to reduce friction of the device when placed in contact with the body, as disclosed and claimed by Applicants, but as an agent for modulating the release of the chemotherapeutic agent from the surface of the polymer coating. The polymers taught in Hunter et al. are selected for their ability to form hydrogen or ionic bonds with the therapeutic agents and not for their low friction and superior durability [0103]. As such, Hunter et al. provides no reason or motivation to one of ordinary skill in the art, to choose the plasticizers claimed by Applicants when attempting to improve the lubricious properties of the polymer

coatings of Applicants.

In summary, Madsen teaches the use of certain polymer coatings for catheters as claimed by Applicants. However, Madsen does not teach the use of plasticizers when coating the device. Madsen only teaches that plasticizers can be used in the wetting solution used to store the medical device. However, the plasticizers taught in Madsen are not the same as the plasticizers claimed in Applicants' claimed method and are not suitable for Applicants' invention.

Furthermore, Hunter et al. teaches that a medical device can be coated with a chemotherapeutic agent, and that a polymer coating can be added to modulate the release of the agent from the surface of the device. Hunter et al. teach that plasticizers may be used in the polymer coating, but do not teach whether glycerol or triethyl citrate, or any plasticizer in particular, are preferable.

"It is impermissible within the framework of 35 U.S.C. §103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what the reference fairly suggests to one skilled in the art." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986). Applicants submit that it is improper for the Examiner to cite Hunter et al. for teaching the use of triethyl citrate as evidence that one of ordinary skill in the art would have known to use Applicants' claimed class of plasticizers in the method, when the Examiner excludes the fact that the reference also cites a class of plasticizers specifically excluded from Applicants' claims as

inoperable for the intended purpose.

In view of the forgoing, Applicants submit that the combination of Madsen, in view of Hunter et al., does not teach each and every element of Applicants' claimed method. Specifically, the combination of references does not teach a method having the steps of applying a coating solution having both a solution of polymers and a specific class of plasticizers having specific chemical properties to a substrate polymer, partially drying the coating, and then curing the coating.

Moreover, even if the combination of references taught all of Applicants' claimed elements, under the new obviousness standard presented in *KSR v. Teleflex*, Applicants submit that the standard requires predictability of the outcome of the combination of elements, which is not the case for the present invention. "A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 (2007).

Hence for the above reasons, Applicants submit that one of ordinary skill would not have found any motivation to combine Madsen, in view of Hunter et al., to solve the problem of providing a coating for a catheter having the improved lubricating properties, because there would have been no reasonable expectation

of success. Applicants therefore respectfully request withdrawal of this rejection.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all currently outstanding rejections, and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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